

REMARKS

Claims 1-4, 7, 9, 10, 12-14, 17, and 19 are currently pending in this application.

REJECTIONS UNDER § 103

Claims 1 and 10 stand rejected under § 103(a) as being unpatentable over U.S. Patent No. 5,746,716 (“Vigil ’716”) in view of U.S. Patent No. 6,009,877 (“Edwards”). Applicants respectfully request reconsideration of this rejection.

Independent claims 1 and 10 recite dispensers “consisting only of dispensers positioned in a single plane.” The Office Action concedes that Vigil ’716 does not disclose this feature. However, the Office Action turns to Edwards for its alleged teaching of “dispensers 90 [that] are located in a single plane (see Fig. 14) to allow for treatment of a limited and precise area of the lumen while minimizing trauma to the lumen and the surrounding area.” As such, the Office Action suggests that it would have been obvious to modify Vigil ’716 to use dispensers in a single plane.

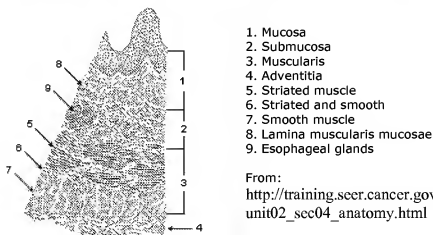
Applicants understand that the Examiner is applying Edwards for the proposition “that when treating a body lumen by inserting needles into the tissue of the lumen[,] it is desirable to minimize the damage that is done to the tissue.”¹ However, this reasoning is flawed because simply following the goal of minimizing tissue injury during treatment does not necessarily result in an *effective* treatment. Although there may be a general motivation to minimize tissue injury during treatment, the Office Action does not recognize the concurrent goal of providing *effective* treatment, which may require inflicting at least some tissue injury.

As such, simply following the goal of minimizing tissue injury would not lead someone of ordinary skill in the art to modify Vigil ’716 in such a way to meet the claimed invention. To take the extreme example, if minimizing tissue injury is the only goal to be achieved, then the device of Vigil ’716 should be modified to have no tissue-penetrating dispensers at all!

In fact, Applicants note that Edwards does not teach simply minimizing tissue injury during treatment. Applicants remind the Examiner that Edwards uses “controlled cell necrosis” as its method of treatment. *See* Edwards, col. 3, lns. 13-19. Thus, in Edwards, causing tissue injury is not merely an unwanted side effect of the treatment, it *is* the treatment.

¹ Office Action, para. 3 on page 2.

As explained in Applicants' prior response, Edwards attempts to reduce tissue injury to the more superficial "mucosal layer" of the esophageal sphincter by, for example, penetrating the RF electrode all the way into the smooth muscle layer (beneath the mucosal layer) and insulating the electrode so as to minimize RF energy being applied to the more superficial mucosal layer. By using this technique of deep RF electrode penetration coupled with electrode insulation, Edwards reduces tissue injury to the mucosal layer of the esophagus while still providing adequate treatment at the smooth muscle cell layer. To facilitate understanding of this technique, a diagram of the esophageal wall is shown below (the layers at the top of the diagram are closer to the inside of the esophagus):



But Edwards does not answer the question of how the Vigil '716 device could be modified to reduce tissue injury while still providing *effective* treatment. As explained in Applicants' prior response, whereas the device of Vigil '716 is designed to treat cardiovascular disease in blood vessels by injecting medicaments into the blood vessels, the Edwards device is designed to treat gastroesophageal reflux disease (GERD) in the esophagus using RF energy delivered via electrodes. Since Edwards discloses nothing about treating cardiovascular disease in blood vessels by injecting medicaments into the blood vessels, how would someone of ordinary skill in the art understand that using dispensers in a single plane, instead of multiple planes over a larger segment of the blood vessel, would still provide adequate treatment? As explained in Applicants' prior response, Edwards' solution for reducing tissue injury by deep RF electrode penetration coupled with electrode insulation would not lead someone of ordinary skill in the art to modify Vigil '716 to use dispensers in a single plane.

For at least these reasons, Applicants respectfully submit that claims 1 and 10, and the claims that depend therefrom, are non-obvious over Vigil '716 in view of Edwards. Accordingly, withdrawal of the rejection is respectfully requested.

Other Rejections

Various other dependent claims in this application stand rejected under § 103(a) as being unpatentable over Vigil '716 in view of Edwards, and further in view of Rammler (WO 94/23787), or Goldberg et al. (U.S. Patent No. 5,480,975), or Casscells et al. (WO 92/11872), or Nabel et al. (U.S. Patent No. 5,328,470).

Without conceding that the Office Action's characterization of these secondary references is correct, Applicants respectfully submit that none of these secondary references disclose dispensers "consisting only of dispensers positioned in a single plane," as recited by claims 1 and 10. Therefore, these secondary references do not cure the above-mentioned deficiencies of Vigil '716 and Edwards. Further, there is nothing in any of these secondary references that would prompt a person of ordinary skill in the art to arrange the dispensers in the manner recited by claims 1 and 10.

For at least these reasons, Applicants respectfully submit that claims 1 and 10, and the claims that depend therefrom, are non-obvious over the references cited in the rejection. Accordingly, withdrawal of the rejections is respectfully requested.

CONCLUSION

Applicants respectfully submit that the present application is in condition for allowance. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of this application.

The Commissioner is authorized to charge all required fees, fees under § 1.17, or all required extension of time fees, or to credit any overpayment to Deposit Account No. 11-0600 (Kenyon & Kenyon LLP).

Respectfully submitted,

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